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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,845	05/29/2001	Chaitan Khosla	300622005500	7453

25225 7590 11/30/2006

MORRISON & FOERSTER LLP  
12531 HIGH BLUFF DRIVE  
SUITE 100  
SAN DIEGO, CA 92130-2040

EXAMINER

ZHOU, SHUBO

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/867,845	<b>Applicant(s)</b> KHOSLA ET AL.	
	<b>Examiner</b> Shubo (Joe) Zhou	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 14-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>8/8/06</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission including the amendments to the claims filed on 11/7/06 has been entered.

However, the amendment to the specification filed 11/7/06 has not been entered because the amendment does not comply with 37 CFR 1.121. The amendments to replace paragraphs on pages 1 and 9 of the specification do not provide markings to show changes made.

Claims 14-22 are currently pending and under consideration.

### ***Specification***

The disclosure is objected to because of the following:

Portions of this application are contained on compact disc(s). When portions of an application are contained on a compact disc, the paper portion of the specification must identify the compact disc(s) and list the files including name, file size, and creation date on each of the compact discs. See 37 CFR 1.52(e). Compact discs comprising appendix A, B, and D filed 3/5/02 are not identified in the paper portion of the specification with a listing of all of the files

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contained on the disc. Applicant is required to amend the specification to identify each disc and the files contained on each disc including the file name, file size, and file creation date.

This objection is reiterated from the previous Office action (the final rejection). Applicant amended the specification in an effort to overcome the objection in the response filed 11/7/06. However, the amendments to the specification have not been entered for reasons set forth above.

Furthermore, it is noted that in the amendment to the specification filed 11/7/06, a new paragraph is to be inserted after paragraph 2 on page 1 of the specification. However, the paragraph numberings of all the subsequent paragraphs are not amended accordingly.

Appropriate correction is required.

### ***Claim Rejections-35 USC § 112***

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 14, 18, 19 and 20 are amended to recite “storing or displaying one or more new strings ... wherein said new string defines a PKS gene capable of producing said

desired polyketide.” Applicant argues in the response filed 11/7/06 that support for the amendment can be found in the specification on pages 50, 52, 59, 63-64, 81, and 87. However, an extensive inspection of the respective paragraphs and other sections of the specification does not find adequate support for the amendment. While paragraph 59 of the specification describes that “[t]his CHUCKLES-coded polyketide library can be stored in a compute file as a set of records;” paragraph 63 of the specification describes writing an alignment into an output, these descriptions are clearly distinct with “storing or displaying one or more new strings ... wherein said new string defines a PKS gene capable of producing said desired polyketide,” as added in the amendment. Thus, the new limitation added is deemed as new matter.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 20 recites “means for receiving a string of alphanumeric symbols representing the structure of said polyketide,” “means for comparing said string to a database of strings of alphanumeric symbols representing polyketides produced producible by PKS genes,” “means for identifying common elements in said string representing the structure of said polyketide with elements in said strings in said database,” and “means for generating and storing or displaying one or more new strings from elements identified in step (c) that have an exact match with said string representing the structure of said polyketide.” These various “means-plus-function” recitations invoke 35 USC 112, sixth paragraph, which states that a claim limitation expressed in

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means-plus-function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language." In the instant case, the specification fails to set forth an adequate disclosure showing what is meant by all the recited "means." Thus, one of skill in the art would reasonably doubt that the inventor, at the time the application was filed, had possession of the claimed invention.

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-22 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 14, 18, 19 and 20 are amended to recite "wherein said new string defines a PKS gene capable of producing said desired polyketide." The phrase "said new string" lacks clear antecedent basis because prior reference is made to "one or more new strings from elements identified in step (c) that have an exact match with said string representing the structure of said desired polyketide." Emphasis is added by the Office. The underline elements above indicate multiple strings are referenced. Thus it is not clear which one of the multiple new strings is referred to by the phrase "said new string." Further, it is not clear whether it is meant that only one, or every one, of the multiple new strings defines a PKS gene capable of producing the desired polyketide.

Claims 15 and 21 recite “[t]he method of claim 14, wherein all possible PKS genes capable of producing the desired polyketide from said database are generated.” Claim 14 recites “a database of strings of alphanumeric symbols representing polyketides producible by PKS genes.” While the polyketides can be produced by PKS genes, it is not indicated that the database per se contains the PKS genes that produce the polyketides. Thus, it is not clear as to how “all possible PKS genes” can be generated and displayed “from said database.”

Claim 20 recites “means-plus-function” limitations, thus invoking 35 USC 112, sixth paragraph. The MPEP 2181(II) states:

*If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112.” In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc).*

In the instant case, the specification does not provide an adequate disclosure showing the structure, material or acts for these “means-plus-function” limitations, for reasons as set forth above. Thus, one skilled in the art would not know what are meant by these “means-plus-function” limitations, and the metes and bounds of the claimed invention are thus not clear.

Furthermore, claim 20 appears to be drawn to a computer-readable medium, which often embodies computer executable program thereon. However the computer readable medium in claim 20 comprises various structural means for performing respective functions. Thus, it is not clear whether claim 20 is drawn to a computer readable medium comprising computer program for performing the series of recited functions or a computer system for performing the functions.


### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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PATENT EXAMINER